



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0576]

Draft Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the draft guidance for industry entitled "Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products" that appeared in the Federal Register of July 2, 2013 (78 FR 39736). The draft guidance document provides sponsors of Investigational New Drug Applications for cellular therapy (CT) and gene therapy (GT) products (referred to collectively as CGT products) with recommendations to assist in designing early-phase clinical trials of CGT products. In the notice, we requested comments on the draft guidance. We are taking this action to allow interested persons additional time to submit comments and to allow for public discussion at the February 25-26, 2014, Cellular, Tissue, and Gene Therapies Advisory Committee meeting, where FDA will present the draft guidance document for review.

DATES: FDA is extending the comment period on the draft guidance. Submit either electronic or written comments by May 9, 2014.

ADDRESSES: Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the draft guidance to the Division of

Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your request. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document

FOR FURTHER INFORMATION CONTACT: Melissa Reisman, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 2, 2013 (78 FR 39736), FDA published a notice announcing the availability of a draft guidance document entitled "Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products." The notice invited comments on the draft guidance by November 22, 2013.

We are extending the comment period for the draft guidance to May 9, 2014. We are taking this action to allow interested persons additional time to submit comments and to allow for public discussion at the April 10-11, 2014, Cellular, Tissue, and Gene Therapies Advisory Committee meeting, where FDA will present the draft guidance document for review.

The Agency believes that this extension will not significantly delay further FDA action on this guidance.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: November 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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